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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,317	12/17/2001	Christian Plank	VOS-22	2272

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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,317	PLANK ET AL.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2005 and 11 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 10/11/2005. The amendment filed on 10/11/2005 is acknowledged. The amendment has been entered. It is noted that the amendment filed 10/11/2005 is in response to a Notice of Informal of Non-compliant Amendment that was issued with respect to the communication filed on 6/17/2005. Applicants arguments filed 6/17/2005 are acknowledged and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claims 1-14, 16 and 17 are currently pending in the application and are addressed herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 12-14, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/19710 (Schacht et al; cited in IDS).

The rejection of claims 1-9, 12-14, 16 and 17 are maintained for the reasons of record set forth in the Office Action mailed on 12/17/2004.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/19710 (Schacht et al; cited in IDS) in view of US Patent 5,863,984 (Doillon et al.).

The rejection of claims 1 and 9-11 are maintained for the reasons of record set forth in the Office Action mailed on 12/17/2004.

Response to Arguments

Applicant's arguments filed 6/15/2005 have been fully considered but they are not persuasive.

With respect to the rejection of claims under 35 USC 102(b), Applicant argues that Schacht does not teach or inherently embody all of the elements of the claims. Specifically, Applicant argues that Schacht does not teach the limitation that the combination comprises a carrier (see pages 8-9 of the arguments filed on 6/17/2005). Applicants refer to p. 4, lines 3-9 of Schacht, which states:

> "[T]he invention provides a nucleic acid carrier vehicle for delivery of nucleic acid material to target cells. . .said carrier vehicle being in the form of a polyelectrolyte complex comprising a nucleic acid-containing cationic polymer core associated with hydrophilic polymer material that forms an outer stabilizing steric shield or coating."

Applicants also refers to claim 48 of Schacht, which recites:

> "[A] synthetic polymer-based carrier vehicle that comprises a polyelectrolyte complex in which a plasmid DNA expression vector. . .is condensed... with a polycationic polymer... that is coupled... to associated hydrophilic polymer material that provides a stabilizing steric shield around the complex."

Applicants assert that Schacht does not use the term "carrier" to refer to a particular element of the complex, but rather, uses the term to refer to the complexes as a whole. Applicant also states that the present application refers to a carrier as, "a body or a substance which can be contacted in vivo or in vitro with cells to be transformed and which carries the complex of nucleic acid(s) and copolymer(s)." (p. 18, lns. 6-8 of the specification). Applicants contend that specific examples of carriers provided in the specification include, "*without limitation*, sponges, powders, gels foils, etc." (Emphasis added; see p. 10, lines 4-7 of the communication filed 6/17/2005).

In response, it is acknowledged that Schacht does refers to the entire complex as a "carrier" as it is intended to be a "carrier" of nucleic acids to target cells. However, this does not indicate that the complex taught by Schacht does not comprise a carrier. It is respectfully pointed out that the instant specification defines "carrier" as follows:

> "A carrier is a body or a substance which can be contacted in vivo or in vitro with cells to be transformed and which carries the complex of nucleic acid(s) and copolymer(s)." (See page 18 of the specification).
>
> Furthermore, page 18 of the specification also indicates,
>
> "The carrier may also be a carrier produced by the cross-linkage of the copolymers according to the invention, preferably in the presence of nucleic acid molecules. Thus, there is, for example, the possibility of introduction of known gene vectors (naked DNA, naked RNA, lipoplexes, polyplexes) and of oligonucleotides and ribozymes, optionally chemically modified, in cross-linked polymers according to the invention."

It is respectfully pointed out that the instant claims do not indicate that the carrier must not be part of the complex itself. In fact, in view of the disclosure on page 18 of the specification (indicated above) and considering that instant claim 12 indicates that the carrier is obtainable by "cross-linkage of a co-polymer", Applicants clearly envision the carrier as being a part of the

complex itself. Therefore, the mere fact that Schacht teaches that the complex comprises the carrier (e.g., HPMA) as a part or the particle itself, does not exclude the reference as art.

Furthermore, Schacht also clearly indicates that the particles can be comprised in a pharmaceutical composition (see claim 50) and indicates that the complex can be in an aqueous solution (e.g., see page 12, lines 1-7). Schacht also teaches that the complex is formulated in a solution comprising borate solution or water/NaOH at pH 7.0-7.6 (page 16, lines 35-36). Therefore, Schacht certainly teaches that the complex is comprised in a composition which includes a "carrier" as defined by the specification.

Therefore, Applicants arguments are not persuasive and the rejection is maintained.

With respect to the rejection of claims under 35 USC 103(a), Applicants argue that (1) Schacht does not describe any carriers at all (which was addressed above), and (2) Doillon does not provide motivation for the use of the disclosed collagen sponge in association with a polymer-nucleic acid complex. It is noted that applicants acknowledge Doillon teaches collagen sponges for delivery of drugs (see pages 10-11 of the 6/17/2005 communication). Applicants also contend that Doillon is concerned with the preparation of collagen sponges so that cells can colonize the sponge in the setting of a wound. Applicants refer to the passage of Doillon (col. 18, lns 13-21) cited by the Examiner, and assert that this passage only discusses increased circulation times with respect to PEG-conjugated liposomes and does not suggest that pegylated collagen sponges should be used for drug delivery (see page 11 of the 6/17/2005 communication). Applicant acknowledges that pegylated liposomes are known and used for drug delivery (see page 11 of the 6/17/2005 communication), but asserts that Doillon does not

suggest using sponges for drug delivery and does not contemplate the use of the sponges for anything other than to provide a material for colonization by cells in wound repair.

In response, it is respectfully pointed out that Doillon explicitly teaches,

> "The present invention relates to porous material useful as temporary wound scaffolds. The porous material consists of sponge-like matrices with a porous and fibrillar structure which can be obtained by freeze-drying a biopolymer dispersion, preferably a collagen dispersion. The biopolymer sponges are then impregnated with a solution of PEG derivatives and allowed to react therewith to obtain composite matrices which have a stable porosity. These matrices can also be used as a support for biologically active molecules to improve wound healing and to reduce wound infection (growth factors and antibiotics, for example). **In addition, these composite matrices can be implanted and used as drug delivery systems** (for antimitotic drugs, for example)." (Emphasis Added; See Column 4, lines 39-55).

Therefore, contrary to Applicants assertion, Doillon does teach that the sponges can be used as drug delivery systems. Furthermore, as applicants acknowledge, PEG-conjugated liposomes are well known as drug delivery vehicles, including nucleic acids.

Furthermore, an in view of the following teaching of Doillon:

> "Thus, the stability of the PEG-modified collagen sponges might be linked to the repulsive properties of PEGs after which their covalent binding to the amino groups of the proteins stabilize the tertiary structure thereof. In addition, with PEG-conjugated liposomes used as drug carriers, the repulsive barrier properties of lipid-conjugated PEG polymer chains and polymer steric stabilization are the basis for their extended in vivo circulation times." (Emphasis added; See column 18, lines 10-21).

It is the Examiner's position that one of ordinary skill in the art would have been motivated to combine the teachings of Schacht and Doillon with a reasonable expectation of success.

Furthermore, Doillon's teaching that the sponge can be used as a drug delivery vehicle, which includes PEG-conjugated liposomes and in view of the fact that PEG-conjugated liposome

was a known nucleic acid delivery vehicle, provides the necessary motivation to combine the teachings of Schacht and Doillon.

Therefore, Applicant's arguments are not persuasive and the rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Anne-Marie Falk

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AU 1635